[redacted]

Dear [redacted]:

This letter is a follow-up to our conversations regarding your pregnancy. I would like to congratulate you once more on your happy news. I want to remind you that we will be calling periodically to check up on your condition through the birth of your baby. This is MDS standard practice for all women who become pregnant while participating in a clinical trial. {Can you please confirm that this is a standard MDS practice for all studies and share with PM USA the procedure in place to "check up on [her] condition."}

~~It has been well documented that smoking~~ The 2001 U.S. Surgeon General's report provides that "women . . . experience unique smoking-related disease risks related to pregnancy" including ~~potential~~ health risks to the developing baby. ~~during a pregnancy can have detrimental effects on the health of the developing baby.~~ To reduce the health risks of smoking, the best thing to do is quit. ~~Due to the fact that smoking can be a difficult habit to quit, we would like to provide you with i~~Information that may be helpful to you can be found at the ~~. A good place to start is the~~ Philip Morris USA website. ~~Please see the following URL:~~ (http://www.philipmorrisusa.com/health_issues/quitting_smoking.asp?source=instant_access). In this section of the web site, you will find things to know if you want to quit smoking, as well as information on the health benefits of quitting and links to other sites that can help smokers quit. You may also want to discuss the issue with your private physician.

~~This site will provide you with links to other sites that provide information on the benefits and possible methods of smoking cessation. Another localized site is the following: http://www.nebquit.com/~~ Why this site? Are there others? Unless the study doctor has recommended this specific site, I would recommend that we do not reference a particular site.

To provide you with additional help, we are willing to provide any smoking cessation counseling in which would like to participate. [Does this mean MDS will pick up the tab? Is this a standard practice for **all** persons who desire to quit smoking during the clinical trial? If so, is the offer qualified in any way? (i.e., how much they will pay, for how long and to what result). Also, did we determine how much the participant will be paid for her participation to date?]

Source: https://www.industrydocuments.ucsf.edu/docs/jnkj0001

Also,

Please feel free to contact me at any time with questions that you may have

Best regards,

Megan McCrory
Clinical Study Manager
MDS Pharma Services

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